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PATENT

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of CHIEN et al.

Serial No.: DIV of 09/881,239

Examiner: Unassigned

Confirmation No.:

Art Unit: Unassigned

Filed: On even date

For: HCV ANTIGEN: ANTIBODY COMBINATION ASSAY

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Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97(b)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,  
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.  
§§1.97 and 1.98.

- ☐ Pursuant to 37 C.F.R. §1.98, a copy of each document cited in the attached Form PTO-1449 is enclosed.
- ☒ No copies of the publications listed on the attached Form PTO-1449 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. 09/881,239 to which the above-identified application claims priority under 35 U.S.C. §120.
- ☐ Publication(s) \_\_\_\_\_ listed on the attached Form PTO-1449 were cited in a foreign search or examination report corresponding to \_\_\_\_\_ application serial no. \_\_\_\_\_ and mailed on \_\_\_\_\_.
- ☐ Enclosed is a copy of a non-English publication(s) \_\_\_\_\_. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

- ☐ Enclosed is a copy of a non-English publication(s) \_\_\_\_\_. English language publication \_\_\_\_ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) \_\_\_\_\_ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) \_\_\_\_\_ cited in the attached Form PTO-1449.
- ☐ Enclosed is a copy of pending patent Application Serial No. \_\_\_\_\_.

This Information Disclosure Statement is filed with the herein divisional application.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO-1449 to the undersigned.

Please direct all written communications in this application to:

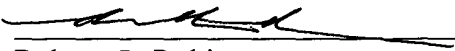
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FORM PTO-1449 (Modified)  
 \ LIST OF PATENTS AND PUBLICATIONS  
 FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
 (Use several sheets if necessary)  
 Sheet 1 of 4

In the Application of CHIEN ET AL.

Serial No.: DIV of 09/881,239

Art Unit: Unassigned

Filed: On even date

Examiner: Unassigned

Title: HCV ANTIGEN: ANTIBODY COMBINATION ASSAY

U.S. PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
	A1	5,350,671	September 27, 1994	Houghton et al.			
	A2	5,712,087	January 27, 1998	Houghton et al.			
	A3	5,843,752	December 1, 1998	Dasmahapatra et al.			
	A4	5,871,904	February 16, 1999	Kashiwkuma et al.			
	A5	5,990,276	November 23, 1999	Zhang et al.			
	A6	6,171,782	January 9, 2001	Houghton et al.			

FOREIGN PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Translation YES NO	
	B1	WO 93/00365	January 7, 1993	PCT				
	B2	WO 94/01778	January 20, 1994	PCT				
	B3	WO 97/44469	November 27, 1993	PCT				
	B4	O 318 216 B2	May 31, 1989	EPO				

Examiner:

Date Considered:

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	B5	0 388 231	September 19, 1990	EPO				
	B6	0 450 931	October 9, 1991	EPO				
	B7	0 472 207 A2	February, 1992	EPO				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Exam. Init.	Ref. Desig.	Description
	C1	Beld et al., "Evaluation of Automated RNA-Extraction Technology and a Qualitative HCV Assay for Sensitivity and Detection of HCV RNA in Pool-Screening Systems," <i>Transfusion</i> <u>40</u> :575-579 (2000)
	C2	Chen et al., "Human and murine antibody recognition is focused on the ATPase/helicase domain, but not the protease domain to the hepatitis C virus non-structural 3 protein," <i>Hepatology</i> <u>28</u> :219-224, 1998
	C3	Chien et al., "Diagnosis of Hepatitis C virus (HCV) Infection Using an Immunodominant Chimeric Polyprotein to Capture Circulating Antibodies: Revaluation of the Role of HCV in Liver Disease," <i>Proc. Natl. Acad. Sci. U.S.A.</i> <u>89</u> :10011-10015 (1992)
	C4	Chien et al., "Use of Recombinant HCV Antigen in the Serodiagnosis of Hepatitis C virus Infection: significant Improvement in HCV Antibody Detection as Compared With the First Generation HCV C100-3 ELISA and the Synthetic Peptide EIA Tests," <i>Journal of Gastroenterology and Hepatology</i> <u>8</u> :S33-39 (1993)
	C5	Chien et al., "Distinct Subtypes of Hepatitis C Virus Defined by Antibodies Directed to the Putative Core, NS4, and NS5 Region Polypeptides," <i>Virol. Hepatitis and Liver Disease</i> <u>3</u> :320-324 (1994)

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Exam. Init.	Ref. Desig.	Description
	C6	Choo et al., "Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome," <i>Science</i> <u>244</u> :359-362 (1989)
	C7	Choo et al., "Hepatitis C Virus: The Major Causative Agent of Viral Non-A, Non-B Hepatitis," <i>British Medical Bulletin</i> <u>46</u> :423-441 (1990)
	C8	Cruse et al., Illustrated Dictionary of Immunology, CRC Press, Boca Raton FL, 1995, page 76
	C9	Ebeling et al., "Recombinant Immunoblot Assay for Hepatitis C Virus Antibody as Predictor of Infectivity," <i>Lancet</i> <u>335</u> :982-983 (1990)
	C10	Houghton et al., "Molecular Biology of the Hepatitis C Viruses: Implications for Diagnosis, Development and Control of Viral Disease," <i>Hepatology</i> <u>14</u> :381-388 (1991)
	C11	Kotwal et al., "Detection of Acute Hepatitis C Virus Infection by ELISA Using a Synthetic Peptide Comprising a Structural Epitope," <i>Proc. Natl. Acad. Sci. U.S.A.</i> <u>89</u> :4486-4489 (1992)
	C12	Kuo et al., "An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non B Hepatitis," <i>Science</i> <u>244</u> :362-364 (1989)
	C13	Pereboeva et al., "Hepatitis C epitopes from phage-displayed cDNA libraries and improved diagnosis with a chimeric antigen," <i>J. Medical Virology</i> <u>60</u> :144-151, 2000
	C14	van der Poel et al., "Infectivity of Blood Seropositive for Hepatitis C Virus Antibodies," <i>Lancet</i> <u>335</u> :558-560 (1990)

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	C15	van der Poel et al., "Confirmation of Hepatitis C Virus Infection by New Four-Antigen Recombinant Immunoblot Assay," <i>Lancet</i> <u>337</u> :317-319 (1991)
	C16	Yao et al., "Molecular Views of Viral Polyprotein Processing Revealed by the Crystal Structure of the Hepatitis C Virus Bifunctional Protease-Helicase," <i>Structure</i> <u>7</u> (11):1353-1363 (1999)

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